



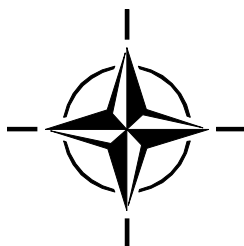
RTO TECHNICAL REPORT

TR-HFM-191

Refractive Surgery: New Techniques and Usability for Military Personnel

(La chirurgie réfractive : Nouvelles techniques
et leur application pour le personnel militaire)

Final Report of Task Group HFM-191.



Published November 2012





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The Research and Technology Organisation (RTO) of NATO

RTO is the single focus in NATO for Defence Research and Technology activities. Its mission is to conduct and promote co-operative research and information exchange. The objective is to support the development and effective use of national defence research and technology and to meet the military needs of the Alliance, to maintain a technological lead, and to provide advice to NATO and national decision makers. The RTO performs its mission with the support of an extensive network of national experts. It also ensures effective co-ordination with other NATO bodies involved in R&T activities.

RTO reports both to the Military Committee of NATO and to the Conference of National Armament Directors. It comprises a Research and Technology Board (RTB) as the highest level of national representation and the Research and Technology Agency (RTA), a dedicated staff with its headquarters in Neuilly, near Paris, France. In order to facilitate contacts with the military users and other NATO activities, a small part of the RTA staff is located in NATO Headquarters in Brussels. The Brussels staff also co-ordinates RTO's co-operation with nations in Middle and Eastern Europe, to which RTO attaches particular importance especially as working together in the field of research is one of the more promising areas of co-operation.

The total spectrum of R&T activities is covered by the following 7 bodies:

- AVT Applied Vehicle Technology Panel
- HFM Human Factors and Medicine Panel
- IST Information Systems Technology Panel
- NMSG NATO Modelling and Simulation Group
- SAS System Analysis and Studies Panel
- SCI Systems Concepts and Integration Panel
- SET Sensors and Electronics Technology Panel

These bodies are made up of national representatives as well as generally recognised 'world class' scientists. They also provide a communication link to military users and other NATO bodies. RTO's scientific and technological work is carried out by Technical Teams, created for specific activities and with a specific duration. Such Technical Teams can organise workshops, symposia, field trials, lecture series and training courses. An important function of these Technical Teams is to ensure the continuity of the expert networks.

RTO builds upon earlier co-operation in defence research and technology as set-up under the Advisory Group for Aerospace Research and Development (AGARD) and the Defence Research Group (DRG). AGARD and the DRG share common roots in that they were both established at the initiative of Dr Theodore von Kármán, a leading aerospace scientist, who early on recognised the importance of scientific support for the Allied Armed Forces. RTO is capitalising on these common roots in order to provide the Alliance and the NATO nations with a strong scientific and technological basis that will guarantee a solid base for the future.

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Published November 2012

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ISBN 978-92-837-0170-5

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Table of Contents

	Page
List of Tables	v
List of Acronyms	vi
Nomenclature	vii
Preface	viii
Foreword	ix
Terms of Reference	xi
Acknowledgements	xiii
HFM-191 Membership List	xiv
 Executive Summary and Synthèse	 ES-1
 Chapter 1 – Introduction	 1-1
1.1 Origin of the Technical Activity	1-1
1.1.1 Background and Justification (Relevance to NATO)	1-1
1.1.1.1 Objectives	1-1
 Chapter 2 – Technique Review	 2-1
2.1 Corneal Refractive Surgery	2-1
2.1.1 Surface Ablation Techniques	2-1
2.1.2 LASIK	2-1
2.1.3 Thermokeratoplasty / Conductive Keratoplasty	2-1
2.1.4 Intrastromal Rings	2-2
2.1.5 Multi-Focal Corneal Ablations	2-2
2.2 Intraocular Surgery	2-2
2.2.1 Clear Lens Extraction	2-2
2.2.2 Phakic Intraocular Lenses	2-2
2.2.3 Accommodative Intraocular Lenses	2-2
2.2.4 Multi-Focal Intraocular Lenses	2-3
2.3 Adjunctive Technology	2-3
2.3.1 Wavefront Measurement	2-3
2.3.2 Femtosecond Laser	2-3
 Chapter 3 – Military CRS Policy	 3-1
3.1 Military Policy on Refractive Surgery	3-1
3.1.1 Member State Policies	3-1

Chapter 4 – Vision Assessment Methods	4-1
4.1 Basic Visual Assessment	4-1
4.2 Additional Tests of Visual Function	4-1
4.3 Special Investigations	4-1
4.4 Post-Operative Visual Performance	4-2
Chapter 5 – Conclusions	5-1
5.1 Further Study	5-1
Chapter 6 – References	6-1

List of Tables

Table		Page
Table 1-1	Techniques and Technologies	1-1
Table 3-1	Techniques and Technologies per Member State: Belgium	3-1
Table 3-2	Techniques and Technologies per Member State: Canada	3-2
Table 3-3	Techniques and Technologies per Member State: Denmark	3-2
Table 3-4	Techniques and Technologies per Member State: France	3-3
Table 3-5	Techniques and Technologies per Member State: Germany	3-3
Table 3-6	Techniques and Technologies per Member State: Greece	3-4
Table 3-7	Techniques and Technologies per Member State: Italy	3-5
Table 3-8	Techniques and Technologies per Member State: Netherlands	3-5
Table 3-9	Techniques and Technologies per Member State: Norway	3-6
Table 3-10	Techniques and Technologies per Member State: Portugal	3-7
Table 3-11	Techniques and Technologies per Member State: Slovenia	3-7
Table 3-12	Techniques and Technologies per Member State: Spain	3-8
Table 3-13	Techniques and Technologies per Member State: Sweden	3-9
Table 3-14	Techniques and Technologies per Member State: United Kingdom	3-9
Table 3-15	Techniques and Technologies per Member State: United States	3-10

List of Acronyms

Epi-LASIK	Epithelial laser-assisted <i>in situ</i> keratomileusis
LASEK	Laser epithelial keratomileusis (also known as Laser sub-epithelial keratectomy)
LASIK	Laser-assisted <i>in situ</i> keratomileusis
PRK	Photorefractive keratectomy

Nomenclature

- **Accommodation:** Ability of the eye to change focal point distances from far to near due to physiologic increases in curvature and thickness of the lens within the eye.
- **Accommodative IOL:** An artificial lens that permits a small amount of change of focus.
- **Chromophore lens:** Lens with light filtering capacity.
- **Corneal epithelium:** The outer layer of the cornea, consisting of about 6 layers of cells attached to a basement membrane.
- **Corneal ectasia:** Progressive pathologic corneal thinning and bulging; causes uncorrectable poor vision.
- **Corneal haze:** clouding of the outer surface of the cornea following surface ablation refractive surgery procedures; caused by under-controlled post surgery inflammatory response.
- **Corneal stroma:** The middle and thickest layer of the cornea, typically around 500 μm in the center, giving the cornea its strength. It consists of highly organized lamellae of parallel collagen fibrils.
- **Excimer laser:** Computer controlled ultraviolet laser that shapes tissue by photoablative DE compensation of molecular bonds. It is used for both surface ablation and LASIK.
- **Femtosecond laser:** Ultrashort infrared wavelength laser that incises tissue by vaporisation. Its use in refractive surgery is to create the LASIK flap.
- **Intraocular surgery:** Placing an artificial lens inside the eye to correct the refractive error. This can be done by extracting the natural lens (CLE), or by leaving the natural lens intact (phakic IOL, also known as ICL) depending on the size of the refractive error.
- **Keratomileusis:** Corneal shaping.
- **Keratoplasty:** Surgical replacement of a portion of the cornea with a piece of cornea of the same size and shape. Also called corneal graft.
- **Keratotomy:** Excision of a portion of the cornea.
- **LASIK:** A partial thickness corneal flap (typically 90 to 160 μm) is created and lifted prior to stromal tissue ablation with the excimer laser. The flap is then placed back over the ablated cornea.
- **Monovision:** One eye corrected for maximal distance acuity and one eye corrected for near vision.
- **Multi-focal IOL:** An artificial lens which permits an extended range of vision by virtue of having more than 1 point of focus.
- **Radial keratotomy:** An early refractive surgical technique in which deep radial incisions were made with a diamond blade into the cornea to flatten its curvature.
- **Surface ablation:** In techniques such as PRK and LASEK, a layer of cells called the corneal epithelium, approximately 50 μm thick, is first removed. The excimer laser is then used to reshape the anterior surface of the cornea.

Preface

In surface ablation techniques such as PRK, Epi-LASIK and LASEK, a layer of cells called the corneal epithelium is first removed. Excimer laser is then used to reshape the anterior surface of the cornea. In LASIK, a partial thickness corneal flap is created and lifted prior to the anterior surface ablation with the excimer laser. The flap is placed back over the ablated cornea. Intraocular surgery may also entail placing a lens inside the eye to correct the refractive error.

Over the last 20 years, unprecedented changes have occurred in the domain of eye surgery. Specifically, the way that refractive errors are treated has undergone a revolution with the advent of lasers that can reshape the cornea. The technology has undergone a series of step changes so that it is now recognised as being one of the safest elective procedures available. Hundreds of thousands of military personnel have undertaken to have corneal refractive surgery in recent years with extremely high levels of satisfaction. However, soldiers and commanders alike have a limited understanding of the different procedures available, the risks to the eye and the impact on occupational vision standards. Moreover, the importance of a fully informed pre-operative assessment and a comprehensive postoperative care are sometimes underestimated. This technical report seeks to clarify the issues surrounding military refractive surgery.

Foreword

The excimer laser represented a paradigm shift in refractive surgery when it was introduced in the late 1980s. This unique ultraviolet laser was able to sculpt the cornea with a microscopic precision not previously seen and without causing underlying tissue damage. Under computer control, the laser could remove a small lenticule of tissue matched precisely to correct a refractive error. This technique was collectively termed Laser Vision Correction (LVC) and refers to all refractive uses of the excimer laser, such as Photorefractive Keratectomy (PRK) and Laser In-Situ Keratomileusis (LASIK). LVC was a significant improvement over previous refractive techniques, such as Radial Keratotomy (RK). RK was quickly rejected for use in operational forces for numerous reasons that were related to the deep corneal incisions intrinsic to the procedure, such as diurnal fluctuation in vision. With the seeming advantages of the excimer laser, military ophthalmologists and researchers began evaluating defence force implications of laser vision correction almost 20 years ago. Through hundreds of studies, a high level of safety and effectiveness of LVC in operational environments became apparent. A careful review of the risks and benefits of LVC by senior officials led to the US DoD Warfighter Refractive Surgery Program in 1999 and the creation of dozens of military treatment centers around the world.

Today well over 100,000 service personnel have undergone LVC to reduce or eliminate their need for optical correction. Military services have enjoyed tremendous success primarily because LVC can increase the combat effectiveness of a fighting force. Examples are numerous. Glasses are not compatible with many of today's specialized weapon systems which require headgear, such as night vision goggles, helmet mounted targeting sights and chemical/biologic protective headgear. None of them perform at optimal levels in conjunction with glasses. Problems include restricted peripheral vision, fogging, incompatibility with swimming/diving, discomfort during prolonged wear, displacement during positive acceleration (+Gz), and reduced clarity in inclement weather. While contact lenses have generally been well received, they can have significant operational problems also. Intolerance to soft contact lenses limits their usefulness, particularly in hot, dusty, or dry environments. Soft lenses are incompatible with chemical/biological headgear. Routine lens hygiene is impractical or impossible during field operations causing personnel to abandon them or extend their wear pattern and risk added complications. Replacement lenses can be difficult to obtain while deployed.

Besides the significant advantages of improving combat effectiveness, we have observed numerous other advantages of performing LVC in the military, some of these are listed below:

- 1) Improved combat readiness. The requirement to maintain optical appliances (spectacles and gas-mask inserts) is an essential component of readiness for combat. By reducing or eliminating the need for optical correction, LVC has had a direct and positive impact on the readiness status of combat forces.
- 2) Increasing the applicant pool. Highly qualified candidates, who were previously excluded because of refractive limits, are now allowed to apply and serve in a variety of occupations. As an example, over 10% of students entering Naval flight training previously underwent LVC. Their selection for flight training was based on their potential to become effective combat pilots when judged against their peers.
- 3) Improved vision. In many individuals, LVC improves vision better than could be achieved before surgery with glasses or contact lenses. This can further enhance combat effectiveness.
- 4) Enhanced quality of life. This is a near universal observation in patients who have undergone successful refractive surgery. Improving the quality of life of a fighting force is not just a noble goal; it can also significantly improve morale and retention.

There have been significant technologic advances in LVC since the Warfighter Refractive Surgery Program was established over 10 years ago. This includes the femtosecond laser for the LASIK flap creation, aberrometry devices to measure all ocular aberrations and wavefront guided procedures which can correct these aberrations. Military researchers have been at the forefront of evaluating these technologies and incorporating successful innovations into clinical practice. Continued research in this regard is vital to ensure that service personnel are offered the best and most appropriate procedures in the future.

We have entered a new era with the introduction of LVC in military forces with its demonstrated ability to reduce the need for optical appliances while maintaining a high level of safety and accuracy. It adds significant and profound value to modern military medicine by not just returning injured personnel to health, but to help them perform their jobs better.

Steve Schallhorn, MD, USN, CAPT (retired)

Terms of Reference

I. ORIGIN

A. Background

Management of refractive errors in military personnel is an important operational issue. New surgical techniques continue to emerge that may provide benefit in managing and correcting refractive errors as well as enabling the expansion of the military applicant pool. A published report of the current surgical techniques available as well as a thorough discussion of the risks and related performance benefits of these procedures on military members is warranted. In Photorefractive Keratectomy (PRK) and its variant surface ablation techniques, the corneal epithelium is first removed and the excimer laser then used to reshape the anterior surface of the cornea. In LASIK, a partial thickness corneal flap is created and lifted prior to the anterior surface ablation with the excimer laser. The flap is placed back over the treated cornea following the ablation. PRK, LASIK and other technologies and techniques are increasingly being performed by some NATO military services on its members and is commonly performed in the civilian community. For some military services, both PRK and LASIK are allowed, some allow only PRK, and some do not allow either. Other refractive surgery procedures should be carefully evaluated for the safety and efficacy in the military environment.

B. Justification (Relevance for NATO)

Management of refractive errors in military personnel is an important operational issue. New surgical techniques continue to emerge that may provide benefit in managing and correcting refractive errors as well as enabling the expansion of the military applicant pool.

II. OBJECTIVES

- 1) Publish a technical report that reviews the clinical risks and benefits regarding PRK, LASIK, and other available refractive surgery procedures and the usability of each in military personnel without diminishing operational effectiveness; update report annually as applicable.
- 2) Publish a technical report that reviews available refractive surgery outcome and quality of vision assessment methodologies and the usability of each in military personnel; update report annually as applicable.
- 3) Publish a summary report of the current refractive surgery policy of each NATO member nation participating in this Technology Working Group (Watch Group); update report annually as applicable.

III. RESOURCES

A. Membership

Chairman: To Be Determined.

Lead Nation: United States.

Nations Willing/Invited to Participate: Belgium, Canada, France, Germany, Italy, Netherlands, Norway, Spain, Turkey, United Kingdom, United States.

B. National and/or NATO Resources Needed

Meeting facility.

Audiovisual and administrative support.

C. RTA Resources Needed

Consultant funding travel expenses for some countries.

IV. SECURITY CLASSIFICATION LEVEL

The security level will be Unclassified/Unlimited.

V. PARTICIPATION BY PARTNER NATIONS

All partners (PfP, MD and preferred Contact Countries) invited.

PfP Nations: All PfP invited.

MD Nations: All MD invited.

ICI Nations: None.

Contact Nations: Australia, Japan, New Zealand.

Acknowledgements

Special thanks for contributions to this technical report made by:

- Dr. (Lt Col) Daniel Emonds (Belgium)
- Dr. (Col) Bruce Bain (Canada)
- Dr. (Col) Scott McLeod (Canada)
- Dr. Pat Hinton (Canada)
- Dr. (Maj) Jan Nybo Nielsen (Denmark)
- Dr. Andreas Patelis (Greece)
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Refractive Surgery: New Techniques and Usability for Military Personnel

(RTO-TR-HFM-191)

Executive Summary

Issue

Corneal surgery to correct refractive errors is highly relevant to military organizations for 3 main reasons. Firstly, by improving uncorrected distance visual acuity, refractive surgery can enable recruits or enlisted personnel to meet uncorrected vision standards for military occupations of their choosing, expanding the applicant pool and enabling individuals to achieve their ambitions. Second, alternative corrective measures, such as contact lenses and spectacles, are not well suited to hostile operational environments and certain military activities and equipment. Thus, refractive surgery in military personnel can enhance operational effectiveness. Third, complicated or inappropriate refractive procedures can cause visual disability and curtail military careers. For this reason, the quality of the service provision should be ensured. Techniques are undergoing constant refinement and innovation, yet the value of new advances in refractive surgery may not be immediately obvious. There is currently no uniformity of policy with respect to refractive surgery in military personnel across NATO.

Purpose

The purposes of this report are to outline the different techniques of refractive surgery available, to evaluate the different approaches to military refractive surgery taken by participating member states and to list the methods for evaluating quality of vision after refractive surgery.

Scope

The scope of this technical report is limited to the current policies of participating member countries, which includes permitted refractive surgical procedures, service provisions and constraints within each state. Ophthalmologists and flight surgeons attached to military service providers from participating NATO member countries and Partners for Peace were invited to submit information regarding refractive surgery in their Armed Forces.

Limitations

Only those countries for which a serving ophthalmologist or flight surgeon was consulted are included in this report, including Belgium, Canada, Denmark, France, Germany, Greece, Italy, Netherlands, Norway, Portugal, Slovenia, Spain, Sweden, the United Kingdom and the United States. It must be stressed that the guidelines and regulations on refractive surgery are effective only insofar as organisations and individuals are prepared to adhere to them. Many service ophthalmologists have witnessed at first hand the consequences of failure to follow the guidelines set out by the occupational health advisers to military organisations.

Considerations

The risks and benefits of refractive surgical procedures are highlighted, with contributions from a panel of Service (or civilian attached) ophthalmologists from NATO member states. The financial costs of refractive surgery are not considered in this report.

Analysis/Results

There is heterogeneity of the degree of service provision and the range of permissible procedures across NATO countries. Clinical governance in refractive surgery is often unsatisfactory, especially in countries where service provision is meagre. This can result in unacceptable procedures being carried out by external providers, or in health care management deviations that produce unacceptably high risks for refractive surgery patients.

Recommendations for Further Study

Further assessment of the risks and benefits of refractive surgical procedures among military occupational groups is needed. A cost-benefit analysis of a refractive surgical service to military organisations is recommended to member states. It is recommended that the cost of inadequate clinical governance in refractive surgery be factored into the overall evaluation.

La chirurgie réfractive : Nouvelles techniques et leur application pour le personnel militaire

(RTO-TR-HFM-191)

Synthèse

Problématique

Les opérations chirurgicales de la cornée destinées à corriger les erreurs de réfraction sont d'un grand intérêt pour les organisations militaires, et ce pour 3 grandes raisons. En premier lieu, en améliorant l'acuité visuelle de loin sans correction, la chirurgie réfractive permet aux jeunes recrues ou militaires du rang de satisfaire aux normes de vision sans correction exigées pour le métier militaire de leur choix, d'où une augmentation du nombre de candidats et la possibilité pour les individus d'atteindre leurs ambitions. En second lieu, les mesures alternatives de correction, comme les lentilles de contact ou les lunettes, ne sont pas bien adaptées à un environnement opérationnel hostile ni à certains matériels ou activités militaires. Par conséquent, le recours à la chirurgie réfractive pour le personnel militaire peut améliorer l'efficacité opérationnelle. En troisième lieu, des interventions compliquées ou inappropriées de chirurgie réfractive risquent d'engendrer des handicaps visuels et d'écourter des carrières militaires. Pour cette raison, la qualité du service fourni doit être garantie. En dépit de constants perfectionnements et innovations techniques, l'intérêt de nouvelles avancées en chirurgie réfractive peut ne pas sauter aux yeux. Il n'existe à l'heure actuelle aucune uniformité des politiques concernant la chirurgie réfractive du personnel militaire au sein de l'OTAN.

Objectif

Les objectifs de ce rapport sont de définir les différentes techniques de chirurgie réfractive disponibles, d'évaluer les différentes approches de chirurgie réfractive militaire entreprises par les Etats membres et de répertorier les méthodes d'évaluation de la qualité de la vision après une chirurgie réfractive.

Portée

La portée du présent rapport technique se limite aux politiques actuelles des Etats membres participants, incluant les procédés autorisés de chirurgie réfractive, les services offerts et les contraintes propres à chaque Etat. Des ophtalmologistes et des médecins qualifiés en médecine aéronautique rattachés aux services militaires compétents d'Etats membres de l'OTAN et des Partenaires pour la Paix ont été invités à fournir des informations relatives à la chirurgie réfractive au sein de leurs forces armées.

Limites

Sont seuls inclus dans ce rapport les pays pour lesquels un ophtalmologiste militaire ou un médecin spécialiste en médecine aéronautique a été consulté, comprenant l'Allemagne, la Belgique, le Canada, le Danemark, l'Espagne, les Etats-Unis, la France, la Grèce, l'Italie, la Norvège, les Pays-Bas, le Portugal, le Royaume-Uni, la Slovaquie et la Suède. Il est important de souligner que les directives et réglementations en matière de chirurgie réfractive ne sont efficaces que dans la mesure où les organisations et individus sont prêts à y adhérer. Plusieurs ophtalmologistes militaires ont été directement témoins des conséquences du non respect de directives établies par les conseillers en santé au travail à l'intention des organisations militaires.

Considérations

Les risques et les avantages des interventions de chirurgie réfractive sont mis en évidence, étayés par les contributions d'une commission d'ophtalmologistes militaires (ou civils rattachés à l'armée) des Etats membres de l'OTAN. Les coûts financiers de la chirurgie réfractive ne sont pas pris en compte dans le présent rapport.

Analyse/Résultats

On observe une hétérogénéité entre le niveau d'offre de services et l'éventail des procédés autorisée d'un pays de l'OTAN à l'autre. La gouvernance clinique en chirurgie réfractive est bien souvent insatisfaisante, en particulier pour les pays où l'offre de tels services est limitée. Cela peut donner lieu à des procédés inacceptables effectués par des prestataires externes, ou encore à des défaillances dans la gestion des soins de santé qui engendrent des risques trop élevés inacceptables pour des patients en chirurgie réfractive.

Recommandations concernant les études à venir

Il est nécessaire de conduire une évaluation plus poussée des risques et avantages des interventions de chirurgie réfractive au sein des groupes professionnels. Il est recommandé aux Etats membres de mener une analyse du rapport coût/avantage d'un service de chirurgie réfractive pour les organisations militaires. Il est également recommandé d'inclure le coût d'une gouvernance clinique inadéquate en chirurgie réfractive dans l'évaluation globale.

Chapter 1 – INTRODUCTION

1.1 ORIGIN OF THE TECHNICAL ACTIVITY

In 2010, a RTO Exploratory Team was organised to investigate the use of refractive surgery in military personnel within the NATO Alliance. The activity proposal was titled: “Refractive Surgery: New Techniques and Usability in Military Personnel”. Follow-on work was recommended and approved to produce this Technical Report.

1.1.1 Background and Justification (Relevance to NATO)

The management of refractive errors in military personnel is an important operational issue. New surgical techniques to correct refractive errors continue to emerge. These can improve combat effectiveness and enable expansion of the military applicant pool, but they are not risk-free. A report of currently available surgical techniques is warranted, including a thorough evaluation of the risks and benefits to military personnel. Refractive surgery can be performed on the cornea, intraocular or both. Both corneal and intraocular procedures are increasingly being performed by some NATO military services on its members and are commonly performed in the civilian community. Some military services allow surface ablation, LASIK and intraocular treatments. Others allow only surface ablation, and some do not allow refractive surgery at all. The safety and efficacy of all refractive surgery procedures should be carefully assessed for the military environment within each member state.

1.1.1.1 Objectives

- 1) To review the clinical risks and benefits of refractive surgical procedures in military personnel.
- 2) To summarise the current refractive surgery policy of each NATO member Nation participating in this Technology Working Group (Watch Group).
- 3) To review clinical outcomes and quality of vision evaluation methods after refractive surgery.
- 4) To update report annually as applicable.

1.1.1.1.1 Techniques and Technologies Currently Used in Refractive Surgery

Table 1-1: Techniques and Technologies.

Corneal Surgery	Intraocular Surgery	Adjunctive Technology
Photorefractive Keratectomy (PRK)	Clear lens extraction	Wavefront measurement
Epithelial Laser-Assisted in situ Keratomileusis (Epi-LASIK)	Phakic intraocular lenses	Femtosecond laser
Laser Epithelial Keratomileusis (LASEK)	Accommodative intraocular lenses	
Laser-Assisted in situ Keratomileusis (LASIK)	Multi-focal intraocular lenses	
Thermokeratoplasty/ Conductive keratoplasty		
Intrastromal rings		
Multi-focal corneal ablations		

INTRODUCTION



Chapter 2 – TECHNIQUE REVIEW

2.1 CORNEAL REFRACTIVE SURGERY

Corneal refractive surgery owes much to the pioneering work of José Ignacio Barraquer, who coined the term ‘keratomileusis’ to describe a technique for re-shaping the cornea with a specialised lathe (‘microkeratome’) to alter the refractive status of the eye [1]. It was recognised in the 1980s that excimer (‘excited dimer’) laser incisions on the corneal surface were highly precise, and soon this technology was used to ablate the corneal surface for refractive purposes [2]. PRK, as surface ablation became known, was often painful and could result in corneal scarring. A new approach was developed in which a flap of cornea was created with a microkeratome and lifted to expose deeper corneal tissue (‘stroma’) for excimer laser ablation [3]. This was called LASIK. Other researchers were using new ultra-high frequency lasers (e.g. femtosecond) to cut corneal tissue with increased precision, and eventually, femtosecond lasers were used in place of the microkeratome to create the corneal flap. The concept of refractive surgery as a military application was advanced in the early 1990s after a group of US Navy SEALs received PRK to improve their operational effectiveness [4]. Since then, there has been a drive to understand the effects of refractive surgery in military and civilian occupations [5].

2.1.1 Surface Ablation Techniques

Surface ablation techniques include PRK, Epi-LASIK and LASEK. LASEK differs from PRK in that the top layer of cells in the cornea (‘epithelium’) is removed by ethanol and replaced after the procedure to reduce pain and scarring. In Epi-LASIK, the top layer of cells is removed by a microkeratome. Surface techniques cost less than flap-based techniques, for which reason they are sometimes preferred over LASIK [6]. In military circles, concerns have been raised about the risk of a traumatic flap dislocation after LASIK surgery. Such a complication, although rare, would almost certainly necessitate the repatriation of a soldier from operational duties. These concerns have resulted in a preference for surface ablation techniques in combat troops in many armies. However, more modern techniques of flap creation, specifically with the femtosecond laser, have been shown to significantly reduce the low risk of traumatic flap displacement [7]. In addition, surface ablation techniques can be associated with corneal scarring (‘haze’), especially at higher levels of myopia. Newer excimer lasers, the use of mitomycin-C as an adjunctive treatment during the procedure, and improved post-operative management have decreased the incidence and severity of corneal haze. However, haze remains a concern in military aviation and night operations, in which decreased contrast sensitivity may adversely affect visual performance.

2.1.2 LASIK

LASIK has undergone a series of refinements since it was conceived. Microkeratomes have become safer and more precise, and femtosecond laser flaps are now a widespread alternative. Concerns about the risks of LASIK that were raised when it was first made available are now much less evident. For example, flap displacement in the early post-operative period used to be relatively common, but is now considered a very rare complication [7]. Early concerns that high gravitational forces could dislodge the flap no longer seem probable. LASIK produces a thinning of the corneal stroma; therefore, it creates a risk for corneal ectasia. Today, better pre-operative diagnostic tools are available and more is known about the safety parameters necessary to minimise the risk of surgically induced corneal ectasia.

2.1.3 Thermokeratoplasty / Conductive Keratoplasty

Thermokeratoplasty and conductive keratoplasty are non-excimer alternative methods of re-shaping the cornea to treat mild hyperopia. Thermokeratoplasty is the application of heat, delivered via a Holmium YAG laser, to the peripheral cornea. Pulses of energy are applied to spots in a concentric ring. This has the

effect of causing the collagen fibres to shrink, thus steepening the cornea and permitting the correction of mild long sight [8]. Conductive keratoplasty is similar, but entails the use of radiofrequency waves to shorten the peripheral corneal fibres [11]. Regression commonly occurs and neither technique have gained wide acceptance.

2.1.4 Intrastromal Rings

The implantation of Polymethylmethacrylate (PMMA) ring segments into the mid-peripheral corneal stroma is a non-laser alternative treatment for mild myopia. However, glare and night vision problems are of particular operational concern with this procedure [9]. Also extrusion of the rings segments is a post-surgical complication that should be considered prior to implantation in military personnel.

2.1.5 Multi-Focal Corneal Ablations

This technique is designed to treat the age-related loss of accommodation (presbyopia) by applying laser to the cornea in differential contours, enabling multi-focal correcting vision at all distances. This procedure increases optical aberrations, reduces contrast sensitivity and produces night vision problems [10].

2.2 INTRAOCULAR SURGERY

Modification of the shape of the cornea is not the only way of altering the refractive power of the eye. The natural crystalline lens inside the eye may be targeted, even in the absence of cataract formation, to correct refractive error. The risk profile of intraocular procedures is different than corneal surgery. Risks include retinal detachment, intraocular bleeding and infection, all of which may cause blindness. However, these severe complications are rare.

2.2.1 Clear Lens Extraction

Removal of the natural crystalline lens from the eye can be combined with artificial lens implantation to change the refractive power. If the natural lens is not opaque with cataract, this procedure is termed 'clear lens extraction'. Generally, such surgery is performed to correct large refractive errors. High refractive error is associated with compromised vision and associated pathologic retinal conditions. Since occupational vision standards in most military organisations preclude entry of recruits with high refractive errors, this procedure is rarely performed on military members. Clear lens extraction is seldom carried out on individuals under the age of 45 because the natural lens can accommodate until approximately this age. The natural ability to accommodate is lost after this surgery.

2.2.2 Phakic Intraocular Lenses

In some cases, high refractive errors in younger patients can be treated while preserving the ability of the natural lens to accommodate by placing slim artificial lenses either in the intraocular space between the cornea and the natural lens ("piggy-back") or by clipping the lens to the front surface of the iris. The risks are similar to other intraocular procedures, with the notable exception of retinal complications, such as retinal detachment and cystoid macular edema. The long-term risk of cataract progression and corneal decompensation (loss of the cornea's ability to regulate its own water content) has been studied and reported in the literature, but remains a concern. Rare complications exist, such as developing a non-reactive dilated pupil, glaucoma, uveitis and infection [12].

2.2.3 Accommodative Intraocular Lenses

Certain artificial intraocular lenses have a hinge movement that permits, at least in theory, a degree of near accommodation. In practice, this is likely to be relatively small [13].

2.2.4 Multi-Focal Intraocular Lenses

Multi-focal lens implantation aims to preserve vision over a range of distances by including differential focus zones within the lens. These zones enable focusing at near, intermediate and far distance. Many patients complain of halo effects, glare at night and reduced contrast sensitivity. While many patients get used to this kind of vision, a few cannot tolerate the lenses, which must then be removed. A multi-focal contact lens trial beforehand can be helpful. On order to qualify for multi-focal lenses, a patient must have minimal corneal astigmatism (a more powerful axis in one corneal meridian than its perpendicular counterpart), as this will induce aberrations [14].

2.3 ADJUNCTIVE TECHNOLOGY

Since it responds to a widespread need, refractive surgery is an area of medicine in which highly sophisticated technology rapidly becomes incorporated into mainstream practice with the aim of improving quality and increasing profitability. Two important advances have been Wavefront technology and the widespread availability of the femtosecond laser.

2.3.1 Wavefront Measurement

Wavefront measurement allows precise measurement of optical aberrations, and is useful for customising laser surgical procedures in which aberrations are higher than normal by accurately targeting the laser to the source of corneal irregularities. The success of this approach is highly dependent upon precise and accurate positioning of the eye, which can be tracked electronically during the surgery. It has the potential to improve visual outcomes in some patients [17]. It also contributes towards our understanding of visual quality, correlating an objective measure of optical aberrations with the subjective experience of visual stimuli [16].

2.3.2 Femtosecond Laser

A high-precision laser with multiple uses in ophthalmology, femtosecond laser is generally viewed as the most effective, most predictable and safest way of cutting the corneal flap for LASIK. It allows much more precise and accurate control of flap thickness and cutting angle than even the most advanced microkeratomes. Thinner and more precise flaps are thought to be safer, minimising the risk of ectasia and of early flap displacement.



Chapter 3 – MILITARY CRS POLICY

3.1 MILITARY POLICY ON REFRACTIVE SURGERY

NATO member states have differing policies on refractive surgery for their Armed Forces, reflecting varied levels of military health provision. One of the drivers for military policy has been that incorrect procedure choice could jeopardise the operational effectiveness of military personnel. For example, an early refractive surgery technique called Radial Keratotomy (RK) involving radial incisions in the cornea, which caused visual acuity to become unstable at altitude. It was deemed incompatible with military service. There is a need for coherent, logical military policies with respect to refractive surgery. This report provides a general overview of military refractive surgery policy among NATO member states.

3.1.1 Member State Policies

For each member state, a summary of current attitudes to refractive surgery is given below. Please note that policies for recruitment may differ from those for retention of serving personnel. Moreover, there is frequently a difference between general military service and Special Forces or aviators, as the visual performance requirements are frequently considered to be higher in the latter groups.

Table 3-1: Techniques and Technologies per Member State: Belgium.

Technique	General Military Service (Special Forces, Aircrew and ATC ¹ Included)	Aviators (Pilots)
PRK	Yes	Not allowed for applicants
LASEK	Yes	Not allowed for applicants
LASIK	Yes	Not allowed for applicants
Thermokeratoplasty/ Conductive keratoplasty	Yes	No
Intrastromal rings	No	No
Multi-focal corneal ablations	Yes	No
Clear lens extraction	No	No
Phakic intraocular lenses	No	Not allowed for applicants
Accommodative intraocular lenses	No	No
Multi-focal intraocular lenses	No	Not allowed for applicants
Wavefront measurement	Yes	Not allowed for applicants
Femtosecond laser	Yes	Not allowed for applicants

¹ Policy for ATC: ESARR 5 (Eurocontrol Safety Regulatory Requirement): EMCR(ATC) 13.1.5: After refractive surgery, applicants may be considered fit provided that:

- a) Pre-operative refraction was less than +5 or -6 dioptres;
- b) Satisfactory stability of refraction has been achieved; (less than 0,75 dioptres variation diurnally);
- c) Examination of the eye shows no post-operative complications;
- d) Glare sensitivity is within normal standards; and
- e) Mesopic contrast sensitivity is not impaired.

Table 3-2: Techniques and Technologies per Member State: Canada.

Technique	General Military Service / Special Forces ¹	Special Forces / Aviators ²
PRK	Yes	Yes
LASEK/Epi-LASIK	Yes	Yes
LASIK	Yes	Yes
Thermokeratoplasty/ Conductive keratoplasty	No	No
Intrastromal rings	No	No
Multi-focal corneal ablations	No	No
Clear lens extraction	No	No
Phakic intraocular lenses	No	No
Accommodative intraocular lenses	No	No
Multi-focal intraocular lenses	No	No
Wavefront measurement	Yes	Yes
Femtosecond laser	Yes	Yes

¹ LASIK is acceptable but PRK, Epi-LASIK and LASEK preferred.

² All procedures for serving aircrew to use wavefront guidance technology. Civilian applicants may use non-wavefront procedures but do so at their own risk and may not be accepted if ophthalmological evaluation determines they do not meet standards.

Table 3-3: Techniques and Technologies per Member State: Denmark.

Technique	General Military Service / Special Forces	Aviators
PRK	Yes	Yes ¹
LASEK/Epi-LASIK	Yes	Yes ¹
LASIK	Yes ²	No
Thermokeratoplasty / Conductive keratoplasty	No formal policy ³	No
Intrastromal rings	No formal policy ³	No
Multi-focal corneal ablations	No formal policy ³	No
Clear lens extraction	No formal policy ³	No
Phakic intraocular lenses	No formal policy ³	No
Accommodative intraocular lenses	No formal policy ³	No
Multi-focal intraocular lenses	No formal policy ³	No
Wavefront measurement	No formal policy ³	No formal policy ³
Femtosecond laser	No formal policy ³	No formal policy ³

¹ Only allowed for non-pilot aircrew.

² Not allowed for Special Forces.

³ Each case will be evaluated individually.

The Danish Armed Forces have no internal ophthalmological clinic or capability. Thus, policy only applies to decision making about medical clearance for entry or continuing military service. All treatment takes place outside the military.

Table 3-4: Techniques and Technologies per Member State: France.

Technique	General Military Service	Special Forces / Aviator
PRK	Yes	Yes
LASEK/Epi-LASIK	Yes	Yes
LASIK	Yes	Yes
Thermokeratoplasty / Conductive keratoplasty	No	No
Intrastromal rings	No	No
Multi-focal corneal ablations	No	No
Clear lens extraction	No	No
Phakic intraocular lenses	No	No
Accommodative intraocular lenses	No	No
Multi-focal intraocular lenses	No	No
Wavefront measurement	Yes	Yes
Femtosecond laser	Yes	Yes

Table 3-5: Techniques and Technologies per Member State: Germany (footnotes overleaf).

Technique ¹	General Military Service	Aviators ²
PRK	Yes	Yes
LASEK/Epi-LASIK	Yes	Yes
LASIK	Yes	Yes Jet pilots must have a residual stromal thickness of 425 µm (325 µm for helicopter and transport pilots)
Thermokeratoplasty / Conductive keratoplasty	No	No
Intrastromal rings	No	No
Multi-focal corneal ablations	No	No
Clear lens extraction	No	No
Phakic intraocular lenses	Yes	No High myopia is incompatible with career as an aviator
Accommodative intraocular lenses	No	No
Multi-focal intraocular lenses	Yes	No
Wavefront measurement	Yes	Yes
Femtosecond laser	Yes	Yes

MILITARY CRS POLICY

¹ Refractive surgery is medically accepted; however, it is not performed at military medical facilities. Payment by the government is only possible by strict medical indication. Generally, refractive surgery is allowed when performed in civilian facilities at the members' expense. Military members are temporarily unfit for duty for several military activities for one year following surgery and must undergo an examination by a military ophthalmologist prior to return to duty.

² All refractive surgery is disqualifying for flying. Waiver is possible by the German Air Force Institute of Aviation Medicine. Refractive surgery for active duty pilots is generally not allowed. Case-by-case recommendations for pilot training applicants may be granted by the German Air Force Institute of Aviation Medicine.

Table 3-6: Techniques and Technologies per Member State: Greece.

Technique	General Military Service	Aviators
PRK	Yes	Yes ¹
LASEK/Epi-LASIK	Yes	Yes ¹
LASIK	Yes	Yes ¹
Thermokeratoplasty / Conductive keratoplasty	No	No
Intrastromal rings	Yes	No
Multi-focal corneal ablations	No	No
Clear lens extraction	No	No
Phakic intraocular lenses	No	No
Accommodative intraocular lenses	No	No
Multi-focal intraocular lenses	No	No
Wavefront measurement	Yes	No
Femtosecond laser	Yes	No

¹ Cadets of the Air Force Academy are allowed any form of refractive surgery (LASIK or PRK). The Air force does not pay for expenses. After surgery examination at the center of aviation medicine is required. 20/20 vision in each eye and maximum spherical equivalent of -1,0 diopters are allowed to fly. Review of LASIK/PRK policy for pilots is pending.

Table 3-7: Techniques and Technologies per Member State: Italy.

Technique	General Military Service / Special Forces	Aviator
PRK	Yes	Yes
LASEK/Epi-LASIK	Yes	Yes
LASIK	Yes	Yes
Thermokeratoplasty / Conductive keratoplasty	No	No
Intrastromal rings	No	No
Multi-focal corneal ablations	No	No
Clear lens extraction	No	No
Phakic intraocular lenses	Yes	No
Accommodative intraocular lenses	No	No
Multi-focal intraocular lenses	No	No
Wavefront measurement	Yes	Yes
Femtosecond laser	No	Yes

Table 3-8: Techniques and Technologies per Member State: Netherlands.

Technique	General Military Service	Special Forces / Aviators ¹
PRK	Yes	Yes ¹
LASEK/Epi-LASIK	Yes	Yes ¹
LASIK	Yes	No
Thermokeratoplasty / Conductive keratoplasty	No	No
Intrastromal rings	No	No
Multi-focal corneal ablations	No	No
Clear lens extraction	No	No
Phakic intraocular lenses	No	No
Accommodative intraocular lenses	No	No
Multi-focal intraocular lenses	No	No
Wavefront measurement	Yes	No
Femtosecond laser	Yes	No

¹ If pre-laser refractive myopia does not exceed -6.0 diopters (JAR3 class 1) and does not exceed -8.00 diopters (JAR3 class 2). In general hyperopia treatments are discouraged.

Table 3-9: Techniques and Technologies per Member State: Norway.

Technique	General Military Service	Special Forces / Aviators
PRK	Yes	Yes Not approved for pilots
LASEK/Epi-LASIK	Yes	Yes
LASIK	Yes ¹	No LASIK is only permitted in medical crewmembers
Thermokeratoplasty / Conductive keratoplasty	No	No
Intrastromal rings	No	No
Multi-focal corneal ablations	No	No
Clear lens extraction	Yes After careful evaluation	No May be waived
Phakic intraocular lenses	Yes After careful evaluation	No
Accommodative intraocular lenses	No	No
Multi-focal intraocular lenses	No	No
Wavefront measurement	Yes	Yes
Femtosecond laser	Yes	Yes

¹ LASIK is not permitted in navigators in the Norwegian Navy.

Surface ablation is preferred refractive surgery procedure. Pre- and post-operative evaluations are required. Refractive surgery for hyperopia is not approved in the Norwegian Air Force.

Table 3-10: Techniques and Technologies per Member State: Portugal.

Technique	General Military Service (aircrew included) / Special Forces	Aviators
PRK	Yes Case-by-case basis	No
LASEK/Epi-LASIK	Yes Case-by-case basis	No
LASIK	Yes Case-by-case basis	No
Thermokeratoplasty / Conductive keratoplasty	No	No
Intrastromal rings	Yes Case-by-case basis	No
Multi-focal corneal ablations	No	No
Clear lens extraction	No	No
Phakic intraocular lenses	No	No
Accommodative intraocular lenses	No	No
Multi-focal intraocular lenses	No	No
Wavefront measurement	Yes	No
Femtosecond laser	Yes	No

Table 3-11: Techniques and Technologies per Member State: Slovenia.

Technique	General Military Service ¹	Special Forces / Aviators
PRK	No	No
LASEK/Epi-LASIK	No	No
LASIK	No	No
Thermokeratoplasty / Conductive keratoplasty	No	No
Intrastromal rings	No	No
Multi-focal corneal ablations	No	No
Clear lens extraction	No	No
Phakic intraocular lenses	No	No
Accommodative intraocular lenses	No	No
Multi-focal intraocular lenses	No	No
Wavefront measurement	No	No
Femtosecond laser	No	No

¹ Due to size of the Slovene Armed Forces, civilian institutions are used for military referrals if needed.

Table 3-12: Techniques and Technologies per Member State: Spain.

Technique	General Military Service ¹ (Special Forces, Aircrew and ATC ² Included)	Aviators
PRK	Yes	Not allowed for applicants
LASEK/Epi-LASIK	Yes	Not allowed for applicants
LASIK	Yes	Not allowed for applicants
Thermokeratoplasty / Conductive keratoplasty	Yes	No
Intrastromal rings	Yes	No
Multi-focal corneal ablations	Yes	No
Clear lens extraction	Yes	No
Phakic intraocular lenses	Yes	Not allowed for applicants
Accommodative intraocular lenses	Yes	No
Multi-focal intraocular lenses	Yes	Not allowed for applicants
Wavefront measurement	Yes	Not allowed for applicants
Femtosecond laser	Yes	Not allowed for applicants

¹ Policy states that “refractive surgery” may be accepted depending on results.

² Policy for ATC: ESARR 5 (Eurocontrol Safety Regulatory Requirement): EMCR(ATC) 13.1.5: After refractive surgery, applicants may be considered fit provided that:

- a) Pre-operative refraction was less than +5 or -6 dioptries;
- b) Satisfactory stability of refraction has been achieved (less than 0,75 dioptries variation diurnally);
- c) Examination of the eye shows no post-operative complications;
- d) Glare sensitivity is within normal standards; and
- e) Mesopic contrast sensitivity is not impaired.

Table 3-13: Techniques and Technologies per Member State: Sweden.

Technique	General Military Service ¹	Special Forces / Aviators
PRK	No	No
LASEK/Epi-LASIK	No	No
LASIK	No	No
Thermokeratoplasty / Conductive keratoplasty	No	No
Intrastromal rings	No	No
Multi-focal corneal ablations	No	No
Clear lens extraction	No	No
Phakic intraocular lenses	No	No
Accommodative intraocular lenses	No	No
Multi-focal intraocular lenses	No	No
Wavefront measurement	No	No
Femtosecond laser	No	No

Table 3-14: Techniques and Technologies per Member State: United Kingdom.

Technique	General Military Service	Special Forces / Aviators
PRK	Yes ¹	Yes ²
LASEK/Epi-LASIK	Yes ¹	Yes ²
LASIK	Yes ¹	Yes ²
Thermokeratoplasty / Conductive keratoplasty	No	No
Intrastromal rings	No ¹	No ²
Multi-focal corneal ablations	No	No
Clear lens extraction	No Intraocular surgical procedures are a bar to entry	No Having undergone non-approved procedures to appear before Medical Board
Phakic intraocular lenses	No	No
Accommodative intraocular lenses	No	No
Multi-focal intraocular lenses	No	No
Wavefront measurement	Yes	Yes
Femtosecond laser	Yes	Yes

¹ Case-by-case basis and subject to single Service requirements.

² For specialist employment unless specifically approved by single Service authorities.

Table 3-15: Techniques and Technologies per Member State: United States.

Technique	General Military Service	Special Forces / Aviators
PRK	Yes	Yes
LASEK/Epi-LASIK	Yes	Yes
LASIK	Yes	Yes
Thermokeratoplasty / Conductive keratoplasty	No	No
Intrastromal rings	No	No
Multi-focal corneal ablations	No	No
Clear lens extraction	Yes Case-by case and only if retinal detachment risk is acceptably low	No
Phakic intraocular lenses	Yes, except US Air Force Case-by-case with careful screening	Yes, except US Air Force and pilots all branches Case-by-case with careful screening No chromophore lenses or monovision
Accommodative intraocular lenses	No	No
Multi-focal intraocular lenses	Yes	No
Wavefront measurement	Yes	Yes
Femtosecond laser	Yes	Yes

Chapter 4 – VISION ASSESSMENT METHODS

4.1 BASIC VISUAL ASSESSMENT

A standard visual assessment before refractive surgery typically consists of measurement of visual acuity and refractive error, slit lamp examination to assess for ocular surface disease, corneal disorders and an examination to exclude sub-clinical pathology such as glaucoma, cataract and retinal pathology. The ocular examination should also include an assessment of ocular alignment as some ocular motility disorders may become manifest following refractive surgery. Cycloplegic refractions are frequently performed in the pre-operative assessments so that accommodation can be neutralised pharmacologically for more precise testing of refractive status. This is especially beneficial for hyperopic patients.

4.2 ADDITIONAL TESTS OF VISUAL FUNCTION

Detailed tests of visual function can be carried out as part of a refractive surgery assessment or as routine screening for occupational performance capability. The testing may include:

- Colour vision;
- Photopic contrast sensitivity;
- Mesopic contrast sensitivity; and
- Visual fields.

In the event of pathology being suspected from a personal medical or a family history of eye disease, more detailed tests may be indicated. Each of these tests may lead to further diagnostic assessments.

4.3 SPECIAL INVESTIGATIONS

Pachymetry (measurement of corneal thickness) is a mandatory preoperative investigation and can be done by ultrasound or by an optical method. Optical measurement systems are integrated in slit-scanning and Scheimpflug-scanning instruments, which offer the advantage of non-contact-measurements and better reproducibility of local data acquisition.

Corneal Topography is an essential diagnostic tool for preoperative detection of contraindications such as keratoconus or other corneal ectatic disorders which would exclude patients from excimer laser surgery. It is mandatory for all patients before surgery and highly advisable for post-operative evaluation. Commonly used instruments are slit-scanning systems with an additional placido-disc or rotating high resolution CCD-cameras.

Scheimpflug-Based Topographic Systems and split scanning systems compute images of the corneal front and back surface. Maps of corneal curvature, elevation or refractive power can be derived from these data in order to obtain a quantitative analysis of corneal shape.

Keratometry and Placido-Based Keratometry are quantitative and qualitative ways of measuring the corneal curvature as a function of its location on the corneal surface. Both methods are incorporated in most modern systems of corneal topography investigation.

Wavefront Measurement Systems, such as the Hartmann-Shack-sensor, the Tscherning-aberrometer or Ray-tracing-systems measure the optical aberrations of the eye for a specified pupil size. They analyse the entire optical characteristics of the eye, not just sphere and cylinder. A wavefront-guided treatment is highly preferable for patients with significant optical aberrations.

Pupil Size has an influence on optical aberrations though wide pupils have not been identified as a definite risk factor for night vision symptoms, such as halo or glare after surgery. It is controversial whether to choose an optical zone based on the preoperative pupil size.

Endothelial-Cell-Counts/Microscopy must be done before and after intraocular refractive surgery, such as phakic intraocular lens implantation or refractive lens exchange. These procedures also necessitate the measurement of anterior chamber depth by ultrasound, Scheimpflug-photography or OCT.

Optical Coherence Tomography (OCT) of the anterior eye computes 3-dimensional reconstructions of cornea, iris, anterior chamber angle and lens through laser interferometry. OCT is no routine investigation. It allows high resolution visualisation of LASIK-flaps or intraocular implants in special cases.

Dry Eye is the most common side-effect after LASIK and may cause reduced visual performance after surgery. The presence of dry eye before surgery should be investigated through a slit lamp exam of the ocular adnexa and cornea. The exam can be augmented with additional tests, such as tear-break-up-time, Schirmer's test or a measurement of tear film osmolarity.

4.4 POST-OPERATIVE VISUAL PERFORMANCE

Military patients, particularly Special Forces and pilots, have greater visual needs than most civilian patients. Subtler visual performance tests can be used to assess their visual status. These can include performing computerised tasks to test dynamic and peripheral contrast sensitivity. For pilots, testing can be extended to flight simulation in order to ensure maximum safety after refractive surgery. Comparison of post-operative visual function test results to pre-operative results may be useful to determine success of surgical outcomes and to guide return to duty decisions [15].

Chapter 5 – CONCLUSIONS

5.1 FURTHER STUDY

The risks and benefits of refractive surgery in military organisations have not been fully evaluated by some NATO Member Nations. The costs of providing comprehensive service provision for military members should be offset against the cost of loss of clinical governance. The concern is that external service providers with limited understanding of military needs may recommend inappropriate procedures and abbreviated post-operative care for military personnel. Therefore, guidance and oversight of total refractive surgery care should be provided by military medical personnel.

Refractive surgery is an evolving discipline with new technology entering the medical care market place at a rapid rate. It is recommended this technology be monitored with periodic update of this report and adding member state policy summaries as they become available.

CONCLUSIONS



Chapter 6 – REFERENCES

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REPORT DOCUMENTATION PAGE																					
1. Recipient's Reference	2. Originator's References RTO-TR-HFM-191 AC/323(HFM-191)TP/469	3. Further Reference ISBN 978-92-837-0170-5	4. Security Classification of Document UNCLASSIFIED/ UNLIMITED																		
5. Originator Research and Technology Organisation North Atlantic Treaty Organisation BP 25, F-92201 Neuilly-sur-Seine Cedex, France																					
6. Title Refractive Surgery: New Techniques and Usability for Military Personnel																					
7. Presented at/Sponsored by Final Report of Task Group HFM-191.																					
8. Author(s)/Editor(s) Multiple			9. Date November 2012																		
10. Author's/Editor's Address Multiple			11. Pages 46																		
12. Distribution Statement There are no restrictions on the distribution of this document. Information about the availability of this and other RTO unclassified publications is given on the back cover.																					
13. Keywords/Descriptors <table border="0"> <tr> <td>Accommodative intraocular lens</td> <td>Excimer laser</td> <td>Laser epithelial keratomileusis</td> </tr> <tr> <td>Corneal ectasia</td> <td>Femtosecond laser</td> <td>Monovision</td> </tr> <tr> <td>Corneal epithelium</td> <td>Keratectomy</td> <td>Multi-focal intraocular lens</td> </tr> <tr> <td>Corneal haze</td> <td>Keratomileusis</td> <td>Photorefractive keratectomy</td> </tr> <tr> <td>Corneal refractive surgery</td> <td>Keratoplasty</td> <td>Radial keratotomy</td> </tr> <tr> <td>Corneal stroma</td> <td>Laser-assisted in situ keratomileusis</td> <td>Surface ablation</td> </tr> </table>				Accommodative intraocular lens	Excimer laser	Laser epithelial keratomileusis	Corneal ectasia	Femtosecond laser	Monovision	Corneal epithelium	Keratectomy	Multi-focal intraocular lens	Corneal haze	Keratomileusis	Photorefractive keratectomy	Corneal refractive surgery	Keratoplasty	Radial keratotomy	Corneal stroma	Laser-assisted in situ keratomileusis	Surface ablation
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14. Abstract <p>The practice of military refractive surgery is recent and continues to evolve. This technology enables war fighting men and women to achieve optimal visual performance in preparation for battle. The various alliance member states have differing attitudes and policies towards refractive surgery for military personnel. All are encouraged to understand the differences between available techniques, appreciate each one's benefits while remaining aware of their limitations.</p>																					





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